IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF DONALD R. OSTERGARD, M.D.

Introduction and Summary

Merely because this Court found some of Dr. Ostergard's opinions in other cases admissible, does not mean that it should do so here. Indeed, this Court has made clear in *Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *4, 18 (S.D.W. Va. Apr. 24, 2015) and more recently in *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 1718836, at *4, 16 (S.D.W. Va. Apr. 28, 2016) that when faced with a different record and different arguments, the Court is merely "informed—though not bound"—by its previous rulings.

A different record and different arguments exist here. Although this Court previously allowed Dr. Ostergard to testify about toxicity and degradation, Dr. Ostergard's recent admissions establish that his opinions on these topics are unsupported, not linked to any issue in these cases, and no different from testimony of Dr. Pandit that the Court has previously excluded. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 711 (S.D.W. Va. 2014). Plaintiffs do not adequately address this new evidence or its significance to the *Daubert* inquiry. And their attempt to distinguish Dr. Ostergard's testimony from that of Dr. Pandit on the grounds that the two experts are generally offered for different topics fails; their opinions on this specific topic are substantively identical.

Nor have Plaintiffs shown that Dr. Ostergard's litigation-driven opinions are relevant here. Although Dr. Ostergard seeks to testify that the placement of mesh products through the vagina is "dangerous" and "violates one of the most basic tenets of surgical teaching," Defs.' Mem. (Dkt. 1997) at 6-7, these opinions are belied by his use of these procedures in clinical practice and his ongoing training of surgical fellows in these very procedures. Plaintiffs' unsupported justifications for Dr. Ostergard's opinions do not change this result and demonstrate the lack of "intellectual rigor" he employs when rendering opinions in the courtroom. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (instructing that an expert must employ in the courtroom "the same level of intellectual rigor that characterizes the practice of an expert" in the expert's field).

And lastly, Plaintiffs did not respond to, and therefore do not oppose, Ethicon's arguments that Dr. Ostergard's opinions on the following topics are inadmissible:

- safer alternative designs (Defs.' Mem. (Dkt. 1997) at 8-9);
- Plaintiffs' assertions that polypropylene causes cancer (*id*. at 9-10);
- FDA regulatory requirements or warnings (*id*. at 11-12); and
- Ethicon's intentions and narrative review of corporate documents (*id*. at 12-14).

See generally Pls.' Opp'n (Dkt. 2167). Accordingly, Plaintiffs have conceded these arguments and the Court should exclude Dr. Ostergard's testimony on these topics. *See, e.g.*, *Edwards v. Ethicon, Inc*., No. 2:12-CV-09972, 2014 WL 3361923, at *27 (S.D.W. Va. July 8, 2014) (excluding expert's opinions regarding safer alternative design where Plaintiffs failed to respond to Ethicon's argument that they were inadmissible).

Ethicon therefore requests that the Court grant its motion to exclude Dr. Ostergard's general-causation testimony, as detailed below and in Ethicon's memorandum.

ARGUMENTS AND AUTHORITIES

I. Dr. Ostergard's Opinions Regarding Toxicity Are Unreliable, Irrelevant, and Indistinguishable from Opinions the Court Has Previously Excluded.

As explained in Ethicon's Memorandum in Support, Dr. Ostergard proposes to testify that polypropylene degrades in vivo, leaching "about 15 additional compounds" that are "toxic" into surrounding tissues. Defs.' Mem. (Dkt. 1997) at 3. Yet he admits that he cannot identify any such toxins, that there are "no studies in relation to polypropylene" that identify such toxins, and that "we do not know if there is increase in adverse events because of it." *Id*. at 3-4. These admissions establish that Dr. Ostergard's opinions on polypropylene's alleged toxicity are not supported by his own knowledge or any scientific literature of which he is aware. And they establish that he cannot link his toxicity opinions to any adverse events alleged by Plaintiffs—meaning his opinions do not "fit" the facts of these cases. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591 (1993). His unsupported opinions are therefore inadmissible as they are both unreliable and irrelevant. *Id*. at 590-91.

In response to Ethicon's challenge, Plaintiffs argue that the Court previously admitted "substantially the same opinions" of Dr. Ostergard on "similar bases in previous mesh cases." Pls.' Opp'n (Dkt. 2167) at 4-5. Ethicon acknowledged in its memorandum that the Court has admitted Dr. Ostergard's toxicity opinions in previous cases, then cited the specific new evidence described above that establishes that his opinions are unsupported *ipse dixit*. Defs.' Mem. (Dkt. 1997) at 3-4. Plaintiffs have not addressed this new evidence, *see* Pls.' Opp'n (Dkt. 2167) at 4-6, and they are "remiss" if they expect the Court to "align with . . . previous rulings when faced with a different record . . ., especially when an expert has issued new reports and given additional deposition testimony," *Winebarger*, 2015 WL 1887222, at *4. That is precisely the situation here.

Instead of directly addressing the new evidence, Plaintiffs attempt to distinguish Dr. Ostergard's opinions from the excluded opinions of Dr. Pandit by arguing that "Dr. Ostergard is not being called to testify as to any specific chemical make-up of the mesh, but, rather, that the chemicals in polypropylene mesh, whatever they may be, cause severe and deleterious effects in the human body." Pls.' Opp'n (Dkt. 2167) at 4-5. Yet if Dr. Ostergard means to testify that mesh is toxic because it degrades and releases chemicals that cause adverse effects in patients, he must support those opinions with reliable, scientific evidence. *Daubert*, 509 U.S. at 590. The fact that "Dr. Pandit was offered as a biomedical engineer and not for general medical testimony, like Dr. Ostergard," Pls.' Opp'n (Dkt. 2167) at 4, does not change the result. Their toxicity opinions are substantively identical and equally unsupported. The Court should exclude Dr. Ostergard's toxicity opinions for the same reasons it excluded Dr. Pandit's—Plaintiffs' characterization of their testimony notwithstanding. *See* Defs.' Mem. (Dkt. 1997) at 3-4; *see also Huskey*, 29 F. Supp. 3d at 711.

Plaintiffs argue further that Dr. Ostergard "supports his opinions on chemical leaching with ample citation to reliable authorities based both on his own scholarship and that of others." Pls.' Opp'n (Dkt. 2167) at 5. Plaintiffs do not identify any such authority, nor do they address Dr. Ostergard's unequivocal testimony that there are "no studies in relation to polypropylene" that identify any toxins released by the mesh, measure any such toxins, or show any increase in related adverse events. *Id*.

Dr. Ostergard's toxicity opinions are not supported, nor are they linked to the facts of Plaintiffs' cases. The Court should exclude them as unreliable and irrelevant under Rule 702.

II. Dr. Ostergard's Degradation-Related Opinions Fail the Fit Test.

Ethicon's "fit" challenge to Dr. Ostergard's degradation opinions is clear: to be admissible, Dr. Ostergard's degradation-related general-causation opinions must logically

advance Plaintiffs' argument that Ethicon's mesh degrades in vivo and that this degradation is capable of causing Plaintiffs' alleged injuries. Defs.' Mem. (Dkt. 1997) at 4-5. Dr. Ostergard's degradation-related opinions do not meet this standard because he unequivocally admitted that neither he nor anyone else of whom he is aware can relate the purported degradation to Plaintiffs' injuries. *Id*. at 5 (quoting Dr. Ostergard's testimony that "[a]t this point in time, we cannot specifically relate degradation to complications in patients").

Plaintiffs acknowledge that Dr. Ostergard's degradation-related opinions are only admissible "if they will advance Plaintiffs' general causation opinions that mesh can and does cause the types of injuries Plaintiffs have sustained." Pls.' Opp'n (Dkt. 2167) at 6. They point to studies on which Dr. Ostergard relies for his opinion that mesh degrades in vivo. *Id*. at 7. They quote several points in Dr. Ostergard's deposition where he offers *opinions* that the purported degradation causes various complications. *Id*. at 6-7. But they do not point to any scientific evidence that would provide the necessary link between Dr. Ostergard's opinion that mesh degrades in vivo and his opinions that this degradation causes clinical sequelae. *See id*. at 6-8. Nor can they, because, as noted above, Dr. Ostergard readily admitted that there is no such support, stating, "At this point in time, we cannot specifically relate degradation to complications in patients." Defs.' Mem. (Dkt. 1997) at 5; *see also id*. (explaining that "since we don't know what the manifestations are, it's very difficult to answer" the question of whether the clinical manifestation of mesh degradation would be variable across patients). This gap between the data on which Dr. Ostergard relies and the opinions he offers renders his degradation opinions inadmissible. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 137 (1997) ("Nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert."). The Court should therefore exclude them under *Daubert*.

III. The Court Should Exclude Dr. Ostergard's Litigation-Driven Opinions Regarding the Safety of Transvaginal Placement of Polypropylene.

Dr. Ostergard's proposed testimony that it is "dangerous" to use mesh in transvaginal procedures is belied by his continued training of fellows in transvaginal procedures involving mesh slings, as well as his recent use of mesh slings in his own practice. Defs.' Mem. (Dkt. 1997) at 6-8. If he truly believed that placing mesh through the vagina "violates one of the most basic tenets of surgical teachings," *id*. at 7, his recent use of such procedures—and ongoing training of surgical fellows in how to perform them—would, by his formulation, constitute surgical malpractice. The inconsistency between the opinions Dr. Ostergard proposes to offer in this litigation and his actual clinical practice weighs heavily against admitting his proposed testimony. *See, e.g.*, *Sanchez v. Boston Scientific Corp*., No. 2:12-CV-05762, 2014 WL 4851989, at *4 (S.D.W. Va. Sept. 29, 2014).

Plaintiffs' response that Dr. Ostergard "used transvaginal mesh only sparingly in his clinical practice" and then only for the treatment of stress urinary incontinence (not pelvic organ prolapse), Pls.' Opp'n (Dkt. 2167) at 8, does not render his opinions admissible. And Plaintiffs' attempt to justify Dr. Ostergard's opinions by stating that "[a]t this point in time, a complete training of urological and gynecological surgeons requires that mesh repairs be taught," *id*. at 8 n.10, fails. They do not offer any support for this assertion and Dr. Ostergard did not qualify his admissions in this way. *See* Defs.' Mem. (Dkt. 1997) at 6-8. The fact remains that Dr. Ostergard's actual practice cannot be squared with his litigation opinions. This is not the intellectual rigor that *Daubert* requires. *See Kumho*, 526 U.S. at 152 (noting that *Daubert* requires that an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert" in the expert's field). His testimony should therefore be excluded as unreliable.

IV. Dr. Ostergard's Opinions Regarding Infection Should Be Excluded in Cases in Which Infection Is Not Alleged.

As Ethicon's memorandum makes clear, Ethicon asks the Court to exclude Dr. Ostergard's infection-related opinions in cases where infection is not at issue. Defs.' Mem. (Dkt. 1997) at 10-11. Contrary to Plaintiffs' argument, Ethicon is not seeking to exclude Dr. Ostergard's infection-related general-causation opinions on the grounds that "Plaintiffs may not eventually be able to carry their burden as to specific causation at trial." *See* Pls.' Opp'n (Dkt. 2167) at 9. If a particular Plaintiff has not alleged infection, then infection-related expert testimony—including general-causation testimony regarding whether mesh is capable of increasing the risk of infection rates—will be irrelevant and therefore inadmissible. *See, e.g.*, *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *5-7 (S.D.W. Va. Feb. 7, 2015).

CONCLUSION

Ethicon asks this Court to grant its Motion to Exclude the General-Causation Testimony of Donald R. Ostergard, M.D., for the reasons stated above and in its memorandum in support of its motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 16, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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